DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

HeartVista, Inc.
% Mr. James Rogers
FDA Regulatory Affairs, Quality Assurance, and Clinical Studies
998 Hamilton Ave.
MENLO PARK CA 94025

December 17, 2014

Re: K142997
Trade/Device Name: RTHawk, or HeartVista Workstation with RTHawk
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic Resonance Diagnostic Device
Regulatory Class: Class II
Product Code: LNH
Dated: November 5, 2014
Received: November 17, 2014

Dear Mr. Rogers:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Robert A Ochs

Robert A. Ochs, Ph.D.
Acting Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142997

Device Name
RTHawk, or HeartVista Workstation with RTHawk

Indications for Use *(Describe)*
The HeartVista Workstation with the RTHawk application software is an accessory to 1.5T and 3.0T whole-body magnetic resonance diagnostic devices (MRDD or MR). The HeartVista Workstation with the RTHawk application software is intended to operate alongside, and in parallel with, the existing MR console to acquire real-time and accelerated images. The HeartVista Workstation with the RTHawk application software is indicated for Cardiovascular MR (CMR) applications.

The HeartVista Workstation with the RTHawk application software produces static and dynamic transverse, coronal, sagittal, and oblique cross-sectional images that display the internal structures and/or functions of the entire body. The images produced reflect the spatial distribution of nuclei exhibiting magnetic resonance. The magnetic resonance properties that determine image appearance are proton density, spin-lattice relaxation time (T1), spin-spin relaxation time (T2) and flow. When interpreted by a trained physician, these images provide information that may assist in the determination of a diagnosis.

The HeartVista Workstation with the RTHawk application software is intended for use as an accessory to the following OEM, MRI system, and software release versions:

- GE Healthcare (GEHC) Signa HDxt 1.5T, 3.0T. Software versions 15 and 16
- GE Healthcare (GEHC) DVMR 1.5T, 3.0T. Software version 24

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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HEARTVISTA

SPECIAL 510(k) Summary
RTHawk
510(k) Number: K142997

Submitted in accordance with the requirements of SMDA 1990 and 21CFR807.92.

1.0 Medical Establishment Registration

Medical Establishment Registration No.: pending

2.0 Contact Information

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3.0 Establishment Name and Address

HeartVista, Inc.
998 Hamilton Ave
Menlo Park, CA 94025

4.0 Submission Date

October 8, 2014, December 16, 2014

5.0 Device Information

Trade/Proprietary Name: RTHawk, or HeartVista Workstation with RTHawk
Common Name: RTHawk, or HeartVista Workstation with RTHawk
Model Number(s):

- 9001 HeartVista Workstation with RTHawk
- 9002 RTHawk

Regulation Number: 892.1000
Regulation Name: Magnetic resonance diagnostic device (MRDD)
Regulatory Class: Class II
Device Classification Name: System, Nuclear Magnetic Resonance Imaging
Classification Panel: Radiology
Classification Product Code(s): LNH

6.0 Predicate Device(s)

510(k) #	Device	510(k) Sponsor	510(k) Clearance Date
K133848	RTHawk, or HeartVista Workstation with RTHawk	HeartVista	6/25/2014

7.0 Device Description

The HeartVista Workstation with RTHawk application software are a software and dedicated hardware product intended to provide a platform for efficient real-time MRI data acquisition, data transfer, image reconstruction, and interactive scan control and display of static and dynamic MR imaging data.

The HeartVista Workstation consists of a stand-alone linux-based computer workstation, color monitor, keyboard and mouse. It is designed to operate alongside, and in parallel with, the existing MR console with no hardware modifications required to be made to the MR system or console. A private ethernet network connects the HeartVista Workstation to the MR scanner computer. When not in use, the HeartVista Workstation may be detached from the MR scanner with no detrimental, residual impact upon MR scanner function, operation, or throughput.

RTHawk is a linux operating system-level software application that is intended to control the MR scanner, acquiring high quality, real-time MRI image data and performing post-processing. The RTHawk software includes optimized image acquisition applications, a pipelined raw data image reconstruction engine, a rich graphical user interface for interactive scan control, real-time adjustment of pulse sequence parameters, and display of reconstructed images, and drivers and protocols for communications with, and control of, the OEM MR scanner console.

RTHawk applications ("apps") support real-time interactive imaging, high-resolution imaging, and system tuning and shimming calibration modules. RTHawk apps are currently optimized for cardiovascular MR (CMR) imaging and measurements.

RTHawk has been designed to comply with the FDA Recognized Consensus Standards listed in the table below, as applicable to device features and components:

Reference #	Title
ANSI/AAMI ES60601-1:2005/ (R)2012 +C1 +A2	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD) Section 14 Programmable Electrical Medical Systems (PEMS)
IEC 60601-2-33 Ed 3.0 (2010-03)	Medical electrical equipment - Part 2-33: Particular requirements for the basic safety and essential performance of magnetic resonance equipment for medical diagnostic (radiology).
MS1-2008	Determination of Signal-to-Noise Ratio (SNR) in Diagnostic Magnetic Resonance Imaging
MS3-2008	Determination of Image Uniformity in Diagnostic Magnetic Resonance Images
MS4-2010	Acoustic Noise Measurement Procedure for Diagnostic Magnetic Resonance Imaging Devices
MS8-2008	Characterization of the Specific Absorption Rate (SAR) for Magnetic Resonance Imaging Systems
NEMA PS3.1 - 3.20 (2011)	Digital Imaging And Communications In Medicine (DICOM) Set.
ISO 14971:2007	Medical devices - Application of risk management to medical devices.

8.0 Indications for Use

The HeartVista Workstation with the RTHawk application software is an accessory to 1.5T and 3.0T whole-body magnetic resonance diagnostic devices (MRDD or MR). The HeartVista Workstation with the RTHawk application software is intended to operate alongside, and in parallel with, the existing MR console to acquire real-time and accelerated images. The HeartVista Workstation with the RTHawk application software is indicated for Cardiovascular MR (CMR) applications.

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9.0 Technological Characteristics Comparison to Predicate Device

Identical.

The RTHawk software is identical to comprised of the following functional modules:

- Acquisition - responsible for the transfer of MR raw data from the MR scanner to the HeartVista Workstation
- Analysis - contains the image post-processing tools
- Application - HeartVista APPs. Each APP is comprised of a pulse sequence, user parameters, a reconstruction pipeline, and a specific user interface
- Information System - the central repository of all relevant MRI system configuration, patient, study, scan, etc., parameters associated with the current patient study
- Reconstruction - responsible for the efficient processing of raw data to generate MR images via a flexible, pipelined topology
- Scan Control - responsible for the real-time network transfer of controlling orders for APPs, APPs parameters modifications, and dynamic information from the MR host in response to user or program requests
- Sequencer - creates and provides a specific set of pulse sequence waveforms to control the MR scanner
- Storage - obtains current patient and scan information, performs non-volatile local storage, exports images and data in DICOM format, and logs events.
- Visualization - implements all aspects of the user iterface, including APP selection, controls to modify APP parameters, image display, graphical slice prescription, and image review, save, and export.

Instructions for use are included within the device labeling, and the information provided enables the user to operate the device in a safe and effective manner.

10.0 Performance Data - Discussion of Non-Clinical Tests

Design controls quality assurance measures during the development of RTHawk include:

- Code reviews
- Design reviews
- Unit and integration level testing
- Verification testing, including System and Manual testing
- Safety testing, including SAR, dB/dt, and acoustic noise
- Performance testing, including SNR and uniformity
- Validation testing

Risk management, compliant with ISO 14971:2007, identified hazards, sequences of events, and resultant harms; developed, implemented, and tested risk-controlling mitigations; and evaluated residual risks.

11.0 Safety Parameters

	RTHawk	Predicate Device
Magnet field strength	1.5T, 3.0T	1.5T, 3.0T
Operating Modes IEC 60601-2-33 (2010-03)	1st Level Operating Mode	1st Level Operating Mode
Safety Parameter Display	SAR, dB/dt	SAR, dB/dt
Max SAR	<4W/kg whole-body	<4W/kg whole-body
Max dB/dt	1st Level Operating Mode	1st Level Operating Mode

12.0 Performance Data - Bench Testing

Clinical images were acquired using RTHawk, and were compared to images acquired on the same patient during the same imaging session using, where possible, equivalent pulse sequences and post-processing as necessary from the predicate device. Images from both devices were evaluated and rated on the basis of diagnostic accuracy and image quality. Where no directly comparable images were available from the predicate device, RTHawk images were evaluated directly based upon radiologist expertise.

Bench testing results for safety parameters of SAR, dB/dt, and acoustic noise were compared to results from K133848 and were consistent with previously reported results.

13.0 Conclusions

Based upon verification and validation testing, safety testing, and compliance with voluntary standards, the Company believes that the RTHawk, or the HeartVista Workstation with the RTHawk application software is substantially equivalent to the predicate device, and does not raise any new questions of safety or effectiveness.